F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399
Email: amahaney@wsgr.com

Bruce R. Genderson (*admitted pro hac vice*)
Aaron P. Maurer (*admitted pro hac vice*)
Rachel Shanahan Rodman (*admitted pro hac vice*)
Adam D. Harber (*admitted pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant and Counterclaimant
SENORX, INC.

IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORP., and HOLOGIC L.P., Plaintiffs, v. SENORX, INC., Defendant.	CASE NO.: 08-CV-0133 RMW **DEFENDANT SENORX, INC.'S NOTICE OF MOTION AND MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY ('142 PATENT, CLAIMS 1 AND 8)**
SENORX, INC., Counterclaimant, v. HOLOGIC, INC., CYTYC CORP., and HOLOGIC L.P., Counterdefendants.	Date: June 25, 2008 Time: 2:00 p.m. Courtroom: 6, 4th Floor Judge: Hon. Ronald M. Whyte

NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD HEREIN:

PLEASE TAKE NOTICE that on June 25, 2008 at 2:00 p.m. (in connection with the claim construction hearing scheduled in this matter), or as soon thereafter as may be heard, in the courtroom of the Honorable Ronald M. Whyte, Defendant SenoRx, Inc. ("SenoRx") will and hereby does move for partial summary judgment that claims 1 and 8 of U.S. Patent No. 6,482,142 (the "'142 patent") are invalid for failure to comply with the provisions of 35 U.S.C. §§ 101 and 112.

SenoRx requests the Court hold claims 1 and 8 of the '142 invalid on the grounds that, as a matter of law, they are inoperable and not enabled since the radiation source recited in claim 1 cannot simultaneously be "within" the claimed outer surface and "spaced apart" from the claimed volume defined by that surface. As claim 8 depends from claim 1, it incorporates all of claim 1's limitations (and flaws as to operability and enablement) as a matter of law.

SenoRx brings the present motion for summary judgment because SenoRx believes that by resolving this pure legal issue (as a matter of claim construction), the Court can dispose of all issues regarding these claims. This motion is made pursuant to Fed. R. Civ. P. 56, Civil Local Rule 56-1, and Judge Whyte's Standing Orders. SenoRx bases its motion upon this Notice of Motion and Motion; the accompanying Memorandum of Points and Authorities In Support Thereof; and the Declaration of Adam Harber In Support of SenoRx's Motion For Partial Summary Judgment of Invalidity.

MEMORANDUM OF POINTS AND AUTHORITIES

This Court is familiar with the claims and prosecution history of the '142 patent, having addressed them in its order denying Plaintiffs' motion for a preliminary injunction. *See* Order Denying Plaintiffs' Motion for Preliminary Injunction ("PI Order") at 13-19. In the preliminary injunction proceedings, as here, SenoRx argued that claim 1 of the '142 patent is invalid because claim 1 requires an impossible configuration. In its PI Order, this Court stated that SenoRx's argument "does raise some significant question regarding whether the claim drafter made a mistake that may be fatal to the claim," *id.* at 16, and found "it to be a very close call as to whether SenoRx has made a substantial showing that the claim is vulnerable to an assertion of invalidity," but declined to decide invalidity on the record before it. *Id.*; *see also id.* at 21 ("There remains a question whether claim 1 of the '142 patent is invalid as indefinite, given the ambiguity regarding the 'volume' versus 'surface' distinction set forth above with regard to the limitation requiring the radiation source to be 'located so as to be spaced apart from the apparatus volume' defined by the outer surface.") The answers to the questions raised by the Court in its PI Order, as discussed below, mandate a finding that claim 1, and claim 8 that depends from claim 1, are invalid.

SenoRx has submitted its *Markman* brief relating to the construction of the critical "apparatus volume" limitation of claim 1 simultaneously with this brief, and will not readdress claim construction here. As the undisputed record plainly demonstrates, claim 1 is inoperable and not enabled under the proper claim construction of "apparatus volume." Therefore, this Court should enter summary judgment of invalidity of claim 1 and dependent claim 8.

ISSUE TO BE DECIDED

Whether claims 1 and 8 of the '142 patent are invalid on the grounds that they are inoperable and not enabled.

SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact

and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1315 (Fed. Cir. 1998). Summary judgment is a useful tool to promote judicial economy and avoid unnecessary trials. *Scripps Clinic & Res. Found., v. Genentech, Inc.*, 927 F.2d 1565, 1570 (Fed. Cir. 1991).

ARGUMENT

A. A Claim Must Be Operable and Enabled To Be Valid.

Operability and enablement are "closely related" questions. *In re Swartz*, 232 F.3d 862, 863 (Fed. Cir. 2000). The utility requirement of 35 U.S.C. § 101 mandates that any patentable invention be useful and, accordingly, the subject matter of the claim must be operable. *See Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992). Utility is a question of fact. *In re Cortright*, 165 F.3d 1353, 1356 (Fed. Cir. 1999). The enablement requirement of 35 U.S.C. § 112, ¶ 1 requires that the specification adequately discloses to one skilled in the relevant art how to make the claimed invention without undue experimentation. *See Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). Lack of enablement is a question of law, based on underlying factual inquiries. *See Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1194 (Fed. Cir. 1999). "If a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement." *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed. Cir. 1999).

B. Claim 1 As Written Is Not Enabled and Is Inoperable.

The operability and enablement of claim 1 depend on the construction of the term "three-dimensional apparatus volume." SenoRx has addressed the construction of this term in its *Markman* briefing, submitted concurrently with this motion for summary judgment. Claim 1 of the '142 patent recites:

> An interstitial brachytherapy apparatus for treating target tissue surrounding a surgical extraction comprising:

> an expandable outer surface defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated;
>
> a radiation source disposed completely within the expandable outer surface and located so as to be spaced apart from the apparatus volume, the radiation source further being asymmetrically located and arranged within the expandable surface to provide predetermined asymmetric isodose curves with respect to the apparatus volume.[1]

See Ex. 1 ('142 patent), Claim 1 (emphases added).[2] The claim thus first introduces a number of components of the claimed apparatus (the expandable outer surface, the three-dimensional apparatus volume, the interstitial void/surgical cavity, and the target tissue), and explains their relationship to each other. The claim then introduces a further component – the radiation source – and describes where the radiation source is located relative to the other components of the device so as to achieve the desired result of asymmetric dosing.

The first element of the claim clearly states that the three-dimensional apparatus volume is defined by the expandable outer surface of the claimed apparatus, *i.e.*, it is the three-dimensional region of space within the expandable outer surface. The second element requires that the radiation source is: 1) inside the expandable outer surface, and 2) spaced apart from the apparatus volume. If claim 1 is construed according to its plain meaning, the claim is inoperable and not enabled because it is impossible for the radiation source to be within the outer surface and, at the same time, also to be "located so as to be spaced apart from the apparatus volume" defined by the outer surface. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956 (Fed. Cir. 1983) ("Because it is for the invention as claimed that enablement must exist, and because the impossible cannot be enabled, a claim containing a limitation impossible to meet may be held invalid under § 112.

---

[1] Claim 8 further requires: "The apparatus of claim 1, wherein the expandable outer surface is sufficiently rigid to deform the target tissue into the shape of the expandable outer surface, causing the predetermined asymmetric isodose curves to penetrate into the target tissue to a prescribed depth."

[2] All citations to exhibits are to exhibits to the Declaration of Adam D. Harber in Support of Defendant SenoRx's Motion for Partial Summary Judgment of Invalidity, submitted herewith.

Moreover, when a claim requires a means for accomplishing an unattainable result, the claimed invention must be considered inoperative as claimed and the claim must be held invalid under either § 101 or § 112 of 35 U.S.C.").

There is no factual dispute about this conclusion; it rests solely on claim construction. As claim construction is a matter of law to be decided by the Court, *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388 (1996), summary judgment of non-enablement and inoperability should be entered if the Court adopts SenoRx's proposed construction, which is discussed at pages 18 to 23 of SenoRx's *Markman* brief submitted herewith.

C. Plaintiffs Cannot Rewrite Claim 1 To Preserve Its Validity.

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citation omitted). "Because the patentee is required to 'define precisely what his invention is'" in the claims, "it is 'unjust to the public, as well as an evasion of the law to construe [the claims] in a manner different from the plain import of [their] terms.'" *Id.* (*quoting White v. Dunbar*, 119 U.S. 47, 52 (1886)). The Patent Act's requirement that a patentee "particularly point[] out" and "distinctly claim[] the subject matter" of his invention, 35 U.S.C. § 112, "'guard[s] against unreasonable advantages to the patentee and disadvantages to others arising from uncertainty as to their [respective] rights.'" *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996) (*quoting Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938)) (alteration in original). Thus, patent claims serve a critical public policy: "'to apprise the public of what is still open to them.'" *Id.* (*quoting McClain v. Ortmayer*, 141 U.S. 419, 424 (1891)). When the "issued patent contains clear structural limitations, the public has a right to rely on those limits in conducting its business activities." *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1425 (Fed. Cir. 1997). The legitimate and reasonable construction of claims serves the same interest; if patent claims could be construed to mean virtually anything – even the opposite of a plain definition contained therein, as Plaintiffs' arguments would have it – the public notice function of patents would be eviscerated. *See White v. Dunbar*, 119 U.S. at 51 (the claims are not "a nose of wax, which may be turned and

twisted in any direction").

Thus, it is well-settled law that neither Plaintiffs nor this Court may rewrite the claims through claim construction, even in the face of a flaw in the claim that renders it invalid. "[C]ourts may not redraft claims, whether to make them operable or to sustain their validity." *Chef Am. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004). Even "a nonsensical result does not require the court to redraft the claims." *Process Control*, 190 F.3d at 1357. In other words, the Federal Circuit has instructed courts to construe the claims in accordance with their plain meaning and other intrinsic evidence, as appropriate, and then to let the chips fall where they may. This is exactly what the Federal Circuit has done in a number of cases, even when this means that the preferred embodiment is not within the scope of the claims, *cf.*, *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583-84 (Fed. Cir. 1996), and even when this results in invalidity.

For instance, in *Allen Engineering Corp. v. Bartell Industries, Inc.*, 299 F.3d 1336, 1348-49 (Fed. Cir. 2002), the Federal Circuit held certain claims invalid, refusing to rewrite them even in light of a patent specification that clearly was to the contrary. The claim in *Allen* contained a limitation of a "gear box [pivoting] only in a plane perpendicular to said biaxial plane." *Id.* at 1349. The description in the patent, on the other hand, described the structure in contrary terms, stating that the "gearbox . . . cannot pivot in a plane perpendicular to the biaxial plane." *Id.* Much as Plaintiffs do here, Allen argued that one of skill in the art would understand that the term "perpendicular" in the claim should be read to mean "parallel" in light of the description of the preferred embodiments of the invention in the specification, which were all parallel. *Id.* The Federal Circuit, however, rejected Allen's attempts to twist the plain meaning of the claim language based on the embodiments disclosed in his specification: "Allen stretches the law too far. It is not our function to rewrite claims to preserve their validity." *Id.*

In *Chef America*, the claim concerned a method of making dough products involving heating an oven to a temperature between 400° F and 850° F. 358 F.3d at 1372. The claim, however, recited "heating the resulting . . . dough to a temperature in the range of about 400° F to

850° F," instead of the oven. *Id.* (emphasis added). This temperature, the Federal Circuit noted, would burn the dough to "a crisp." *Id.* The Federal Circuit refused to read "dough" to mean "oven," stating that the "ordinary, simple English words [in the claim,] whose meaning is clear and unquestionable" trumped the nonsensical result. *Id.* at 1373. The words in the claim "mean exactly what they say. The dough is to be heated to the specified temperature." *Id.*

The same result is required here. The ordinary, simple English words in claim 1 of the '142 patent make clear that the expandable surface defines the apparatus volume; it is plainly not the case, despite Plaintiffs' attempts to contort the ordinary meaning of the language, that the apparatus volume and surface are the same thing. They are different. The ordinary, simple English words of claim 1 also make clear that the apparatus volume "fill[s]" the "void created by the surgical extraction of diseased tissue." Thus, the limitation that the radiation source be "located so as to be spaced apart from the apparatus volume" means that the radiation source is located outside of the expandable outer surface. In this way – and only in this way – do the words of the claim "mean exactly what they say." *Chef Am.*, 358 F.3d at 1373. Had Plaintiffs here wanted claim 1 to read "a radiation source disposed completely within and spaced apart from the expandable outer surface" (essentially their current construction of the "spaced apart" limitation), they clearly could have drafted or amended the claim to so read. In fact, Plaintiffs said exactly that in claim 9 of the '142 patent. *See* Ex. 1 ('142 patent), claim 9 ("an expandable outer surface . . . defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated; a radiation source disposed completely within and spaced apart from the expandable outer surface . . . ."). However, they chose not to in claim 1, and, as in *Chef America*, must be held to the consequences.

The same result was reached in *Process Control*. As here, the claim in *Process Control* explicitly defined a term that, given the term's definition, meant the claim recited an impossibile, nonsensical limitation. *Process Control*, 190 F.3d at 1357. The Federal Circuit rejected the patentee's request to construe the term in accordance with the specification or in accordance with

what was intended to have been claimed. *Id.* at 1356-57. Instead, the Federal Circuit held that the claim language trumped any other evidence allegedly supporting a contrary construction:

> The district court's attempt to use the written description to circumvent the plain language of the claim and the clear definition of the disputed claim language found therein was inappropriate. . . . [W]e do not permit courts to redraft claims. . . . Where, as here, the claim is susceptible to only one reasonable construction, the canons of claim construction cited by [the patentee] are inapposite, and we must construe the claims based on the patentee's version of the claim as he himself drafted it.

Id. at 1357 (emphasis added). As a result, the court in *Process Control* invalidated the claim as inoperable, holding that it recited an impossibility. *Id.* at 1359 ("[W]hen an impossible limitation, such as a nonsensical method of operation, is clearly embodied within the claim, the claimed invention must be held invalid.").

The Northern District of California recently cited *Process Control* in a case raising the exact question at issue here. In *Applera Corp. v. Illumina, Inc.*, No. C-07-02845, 2008 WL 501391 (N.D. Cal. Feb. 21, 2008), the court recognized that the specification was inconsistent with the claims, but nonetheless held that:

> After much study of the specification, the undersigned judge is of the view that the inventor, patent counsel, and the examiner all made a drafting error. While it is tempting to just fix it up in the claim construction process, that temptation would be dangerous course, for it should be up to the PTO in the first instance to amend claims.

Id. at *5. Similarly, Plaintiffs here should not be allowed to rewrite their claims and escape invalidity.

The Court in its PI Order suggested claim 1 could be read to require that the apparatus volume defines the inner boundary of the target tissue to be treated, and that this created an ambiguity in the claim that might distinguish *Process Control*. PI Order at 15-16. In particular, the Court reasoned that it is undisputed that the outer surface of the balloon touches the target tissue; therefore the claim in referring to the "apparatus volume" defining the inner boundary of the tissue could be equating the surface and the volume. *Id.* at 15. Respectfully, the Court's conclusions do not follow from its premise.

In context, there is no inconsistency between the apparatus volume defining an inner

boundary of the target tissue and the apparatus volume being a distinct and separate structure from the outer surface (and defined by that surface). The first element of claim 1 recites, on the Court's reading, that the apparatus volume (1) fills the void created by surgical extraction of diseased tissue and (2) defines an inner boundary of the target tissue being treated. When devices of this type are used, however, these two functions are interrelated and are essentially two sides of the same coin. When the apparatus volume fills the void left by surgical removal of diseased tissue, the device's balloon is completely inflated and in contact with the inner boundary of the target tissue. As a result, for all practical purposes, the inner boundary of the target tissue is the same as the outer boundary of the void left after tissue has been removed – both are the edge of the cavity that has been filled by the volume. Accordingly, by filling the void left by the surgical extraction of tissue, the apparatus volume also is necessarily defining an inner boundary of the target tissue to be treated – where the "filling" of the void stops, the "defining" of the boundary necessarily begins. Thus, there is no inconsistency between the plain meaning of "apparatus volume" and the apparatus volume defining the inner boundary of the target tissue.

Moreover, as discussed in SenoRx's *Markman* brief, another plausible reading of the claim is that the expandable outer surface, and not the apparatus volume, defines the inner boundary of the target tissue. But either way, this possible ambiguity does not affect the plain definition of apparatus volume in the claim, and has nothing to do with the issue at hand. Whether the boundary of tissue to be treated is defined by the volume or by the surface, the claim plainly states that the surface defines the volume, and that they are not the same thing.

For these reasons, it is respectfully submitted that *Process Control* governs the result here, and Plaintiffs should be precluded from redrafting their claim through the claim construction process to avoid inoperability and invalidity.

CONCLUSION

Since the radiation source of claim 1 cannot simultaneously be "within" the outer surface and "spaced apart" from the volume defined by that surface, claim 1 is inoperable and invalid. As claim 8 depends from claim 1, it too should be declared invalid for the same reasons.

Respectfully Submitted,

Dated: May 21, 2008

WILSON SONSINI GOODRICH & ROSATI
Professional Corporation

By: /s/ F.T. Alexandra Mahaney
F.T. Alexandra Mahaney
amahaney@wsgr.com

Attorneys for Defendant and Counterclaimant
SENORX, INC.

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Kirsten Blue, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On May 21, 2008, I served a copy(ies) of the following document(s):

DEFENDANT SENORX, INC.'S NOTICE OF MOTION AND MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY ('142 PATENT, CLAIMS 1 AND 8)

on the parties to this action by the following means:

Henry C. Su (suh@howrey.com) Katharine L. Altemus (altemusk@howrey.com) HOWREY LLP 1950 University Avenue, 4th Floor East Palo Alto, CA 94303 Telephone: (650) 798-3500 Facsimile: (650) 798-3600	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP
Matthew Wolf (wolfm@howrey.com) Marc Cohn (cohnm@howrey.com) HOWREY LLP 1229 Pennsylvania Avenue, NW Washington, DC 20004 Telephone: (202) 783-0800 Facsimile: (202) 383-6610	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP

☒ (BY MAIL) I placed the sealed envelope(s) for collection and mailing by following the ordinary business practices of Wilson Sonsini Goodrich & Rosati, 12235 El Camino Real, Ste. 200, San Diego, CA. I am readily familiar with WSGR's practice for collecting and processing of correspondence for mailing with the United States Postal Service, said practice being that, in the ordinary course of business, correspondence with postage fully prepaid is deposited with the United States Postal Service the same day as it is placed for collection.

☒ (BY ELECTRONIC MAIL) I caused such document(s) to be sent via electronic mail (email) to the above listed names and email addresses.

☒ (BY CM/ECF) I caused such document(s) to be sent via electronic mail through the Case Management/Electronic Case File system with the U.S. District Court for the Northern District of California.

I declare under penalty of perjury under the laws of the United States that the above is true and correct, and that this declaration was executed on May 21, 2008.

Kirsten Blue

F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399
Email: amahaney@wsgr.com

Bruce R. Genderson (*admitted pro hac vice*)
Aaron P. Maurer (*admitted pro hac vice*)
Rachel Shanahan Rodman (*admitted pro hac vice*)
Adam D. Harber (*admitted pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant and Counterclaimant
SENORX, INC.

IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORP., and HOLOGIC L.P., Plaintiffs, v. SENORX, INC., Defendant.	CASE NO.: 08-CV-0133 RMW **DECLARATION OF ADAM D. HARBER IN SUPPORT OF DEFENDANT SENORX, INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY ('142 PATENT, CLAIMS 1 AND 8)**
SENORX, INC., Counterclaimant, v. HOLOGIC, INC., CYTYC CORP., and HOLOGIC L.P., Counterdefendants.	Date: June 25, 2008 Time: 2:00 p.m. Courtroom: 6, 4th Floor Judge: Hon. Ronald M. Whyte

I, Adam D. Harber, declare that I am an associate at the law firm of Williams & Connolly LLP, admitted pro hac vice to practice before this Court in the above-captioned matter. I serve as outside counsel for Defendant SenoRx, Inc. ("SenoRx"). The following declaration is based on my personal knowledge, and if called upon to testify, I could and would competently testify as to the matters set forth herein.

1. Attached hereto as Exhibit 1 is a true and correct copy of U.S. Patent No. 6,482,142.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: May 21, 2008

By: _____
Adam D. Harber

Exhibit 1

US006482142B1

(12) **United States Patent**
Winkler et al.

(10) **Patent No.: US 6,482,142 B1**
(45) **Date of Patent: Nov. 19, 2002**

(54) **ASYMMETRIC RADIATION DOSING APPARATUS AND METHOD**

(75) Inventors: **Rance A. Winkler**, Atlanta; **Timothy J. Patrick**, Alpharetta, both of GA (US)

(73) Assignee: **Proxima Therapeutics, Inc.**, Alpharetta, GA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/464,727**

(22) Filed: **Dec. 16, 1999**

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/293,524, filed on Apr. 15, 1999, which is a continuation-in-part of application No. 08/900,021, filed on Jul. 24, 1997, now Pat. No. 5,913,813.

(51) **Int. Cl.**[7] **A61N 5/00**
(52) **U.S. Cl.** **600/3**
(58) **Field of Search** 600/1–8

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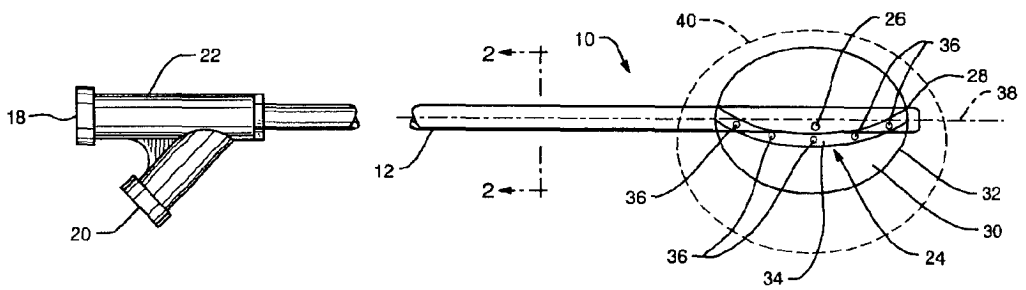
Primary Examiner—John P. Lacyk
(74) *Attorney, Agent, or Firm*—Thomas J. Engellenner; Ronald E. Cahill; Nutter McClennen & Fish LLP

(57) **ABSTRACT**

An interstitial brachytherapy apparatus of the invention delivers radioactive emissions in an asymmetric fashion to target tissue surrounding a surgical extraction site. The apparatus includes an expandable outer surface element defining an apparatus spatial volume, a radiation source disposed within the apparatus volume, and a means for providing predetermined asymmetric isodose curves within the target tissue. In one configuration, asymmetric isodose curves are created in the target tissue by shaping or locating the radiation source so as to be asymmetrically placed with respect to a longitudinal axis of the apparatus. In other configurations, asymmetric radiopaque shielding is provided between the radiation source and the target tissue. A surgical procedure using the apparatus is also described.

14 Claims, 4 Drawing Sheets



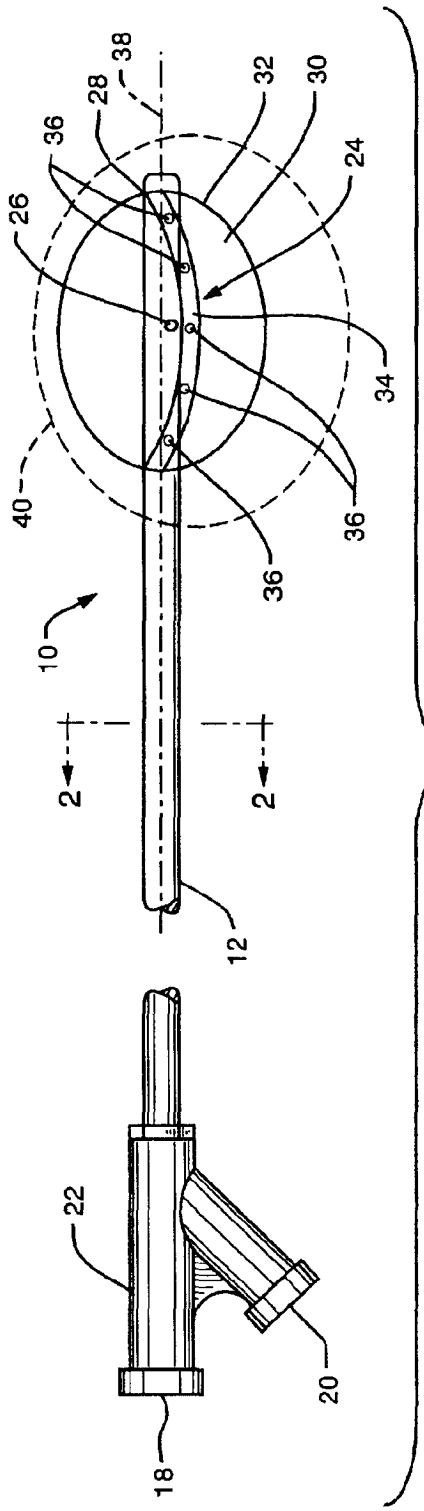


FIG. 1

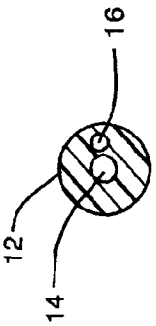


FIG. 2

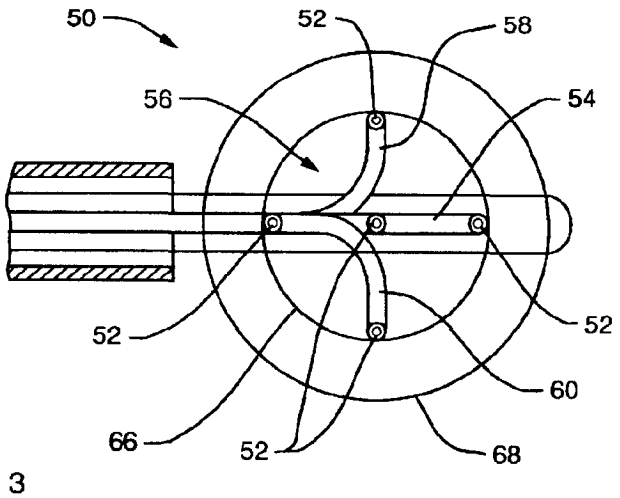


FIG. 3

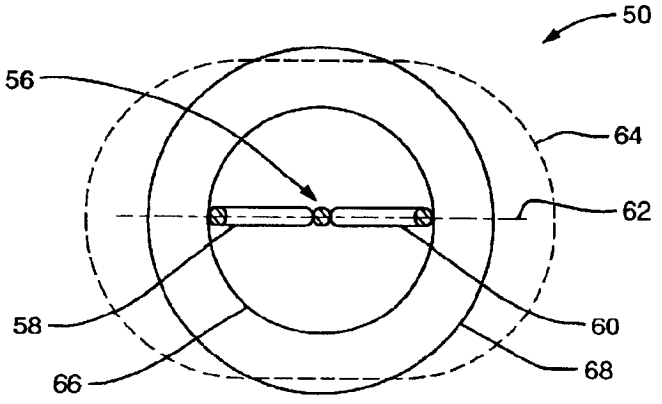


FIG. 3A

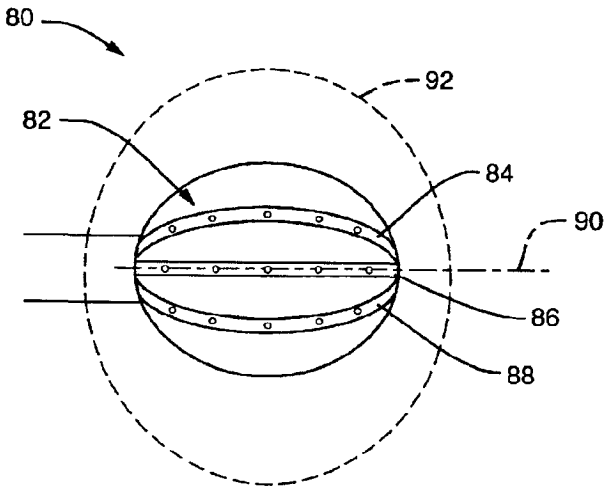


FIG. 4

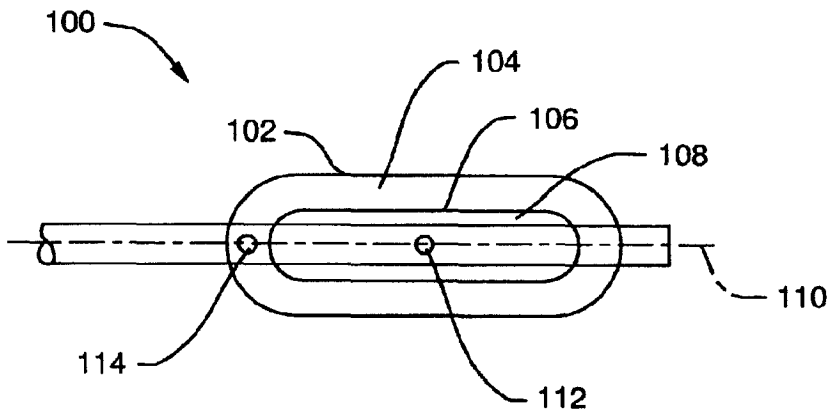

100
104
102
106
108
110
114
112

FIG. 5

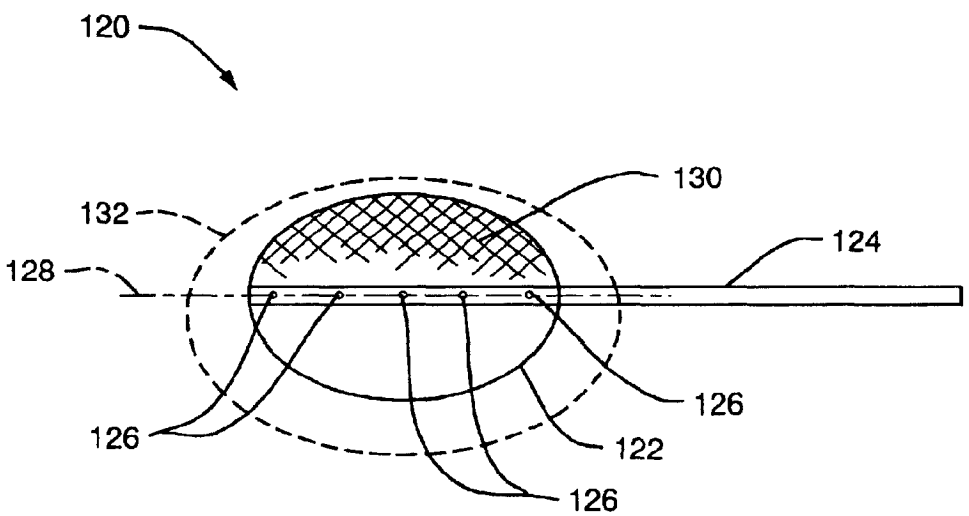

120
130
132
124
128
126
126
122
126

FIG. 6

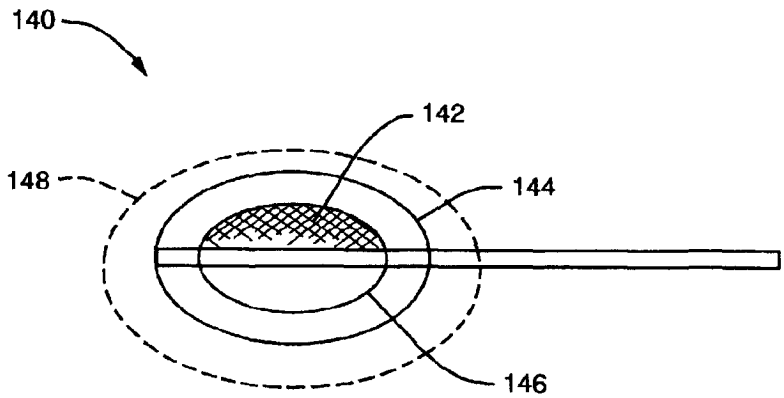


FIG. 7

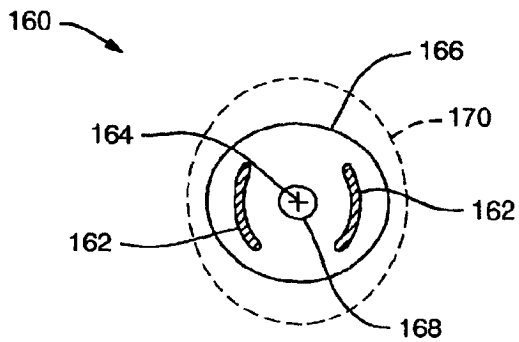


FIG. 8

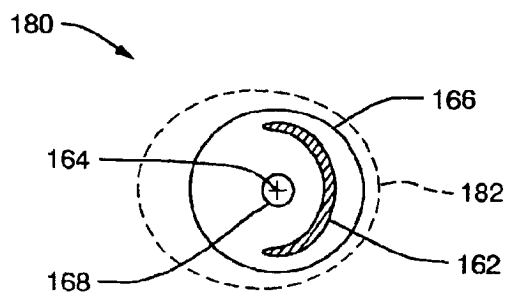


FIG. 9

ASYMMETRIC RADIATION DOSING APPARATUS AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of co-pending U.S. patent application Ser. No. 09/293,524, filed Apr. 15, 1999, pending which is a continuation-in-part U.S. patent application Ser. No. 08/900,021, filed Jul. 24, 1997 (now issued as U.S. Pat. No. 5,913,813 to Williams et al.); the contents of these applications are specifically incorporated herein by reference.

BACKGROUND OF THE INVENTION

The, invention relates generally to an apparatus for use in treating proliferative tissue disorders, and more particularly to an apparatus for the treatment of such disorders in the body by the application of radiation.

Malignant tumors are often treated by surgical resection of the tumor to remove as much of the tumor as possible. Infiltration of the tumor cells into normal tissue surrounding the tumor, however, can limit the therapeutic value of surgical resection because the, infiltration can be difficult or impossible to treat surgically. Radiation therapy can be used to supplement surgical resection by targeting the residual tumor margin after resection, with the goal of reducing its size or stabilizing it. Radiation therapy can be administered through one of several methods, or a combination of methods, including external-beam radiation, stereotactic radiosurgery, and permanent or temporary interstitial brachytherapy. The term "brachytherapy," as used herein, refers to radiation therapy delivered by a spatially confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site. Owing to the proximity of the radiation source, brachytherapy offers the advantage of delivering a more localized dose to the target tissue region.

For example, brachytherapy is performed by implanting radiation sources directly into the tissue to be treated. Brachytherapy is most appropriate where 1) malignant tumor regrowth occurs locally, within 2 or 3 cm of the original boundary of the primary tumor site; 2) radiation therapy is a proven treatment for controlling the growth of the malignant tumor; and 3) there is a radiation dose-response relationship for the malignant tumor, but the dose that can be given safely with conventional external beam radiotherapy is limited by the tolerance or normal tissue. In brachytherapy, radiation doses are highest in close proximity to the radiotherapeutic source, providing a high tumor dose while sparing surrounding normal tissue. Interstitial brachytherapy is useful for treating malignant brain and breast tumors, among others.

Interstitial brachytherapy is traditionally carried out using radioactive seeds such as ^{125}I seeds. These seeds, however, produce inhomogeneous dose distributions. In order to achieve a minimum prescribed dosage throughout a target region of tissue, high activity seeds must be used, resulting in very high doses being delivered in some regions in proximity to the seed or seeds which can cause radionecrosis in healthy tissue. One attempt to address this problem, at least with respect to limiting dosages to critical organs near the radioactive seed site, has been to provide a shield directly on a portion of the seed or on an applicator that holds the seed to shield the particularly sensitive tissue. (E.g., Nath et al., Development of an ^{241}Am Applicator for Intracavitary Irradiation of Gynecologic Cancers, *Intl. J. Radiation Oncology Biol. Phys.*, Vol., 14, pp. 969–978.) While this approach may be appropriate for some applications, it may still be overly "hot" for treating proximate tissue on the unshielded side of the seed, while not providing an effective dose on the shielded side of the seed.

Williams U.S. Pat. No. 5,429,582, entitled "Tumor Treatment," describes a method and apparatus for treating tissue surrounding a surgically excised tumor with radioactive emissions to kill any cancer cells that may be present in the tissue surrounding the excised tumor. In order to implement the radioactive emissions, Williams provides a catheter having an inflatable balloon at its distal end that defines a distensible reservoir. Following surgical removal of a tumor, the surgeon introduces the balloon catheter into the surgically created pocket left following removal of the tumor. The balloon is then inflated by injecting a fluid having one or more radionuclides into the distensible reservoir via a lumen in the catheter.

The apparatus described in Williams solves some of the problems found when using radioactive seeds for interstitial brachytherapy, but leaves some problems unresolved. The absorbed dose rate at a target point exterior to a radioactive source is inversely proportional to the square of the distance between the radiation source and the target point. s a result, where the radioactive source has sufficient activity to deliver a prescribed dose, say 2 centimeters into the target tissue, the tissue directly adjacent the wall of the distensible reservoir, where the distance to the radioactive source is very small, may still be overly "hot" to the point where healthy tissue necrosis may result. In general, the amount of radiation desired by the physician is a certain minimum amount that is delivered to a region up to about two centimeters away from the wall of the excised tumor. It is desirable to keep the radiation that is delivered to the tissue in the target treatment region within a narrow absorbed dose range to prevent over-exposure to tissue at or near the reservoir wall, while still delivering the minimum prescribed dose at the maximum prescribed distance from the reservoir wall. It is also desirable, at least in some applications, to provide these advantages while tailoring the radiation dosage to avoid fully dosing sensitive tissue or to reduce the amount of radiation that escapes the patient's body.

There its still a need for an instrument which can be used to deliver radiation from a radioactive source to target tissue within the human body with a desired intensity and at a predetermined distance from the radiation source without over-exposure of body tissues disposed between the radiation source and the target, and with the ability to shape the radiation dose to protect sensitive tissue or to protect against radiation exposure outside of the patient's body which may affect healthcare providers or others who might come close to the patient.

SUMMARY OF THE INVENTION

The present invention solves the problems described above by providing an interstitial brachytherapy apparatus for delivering radioactive emissions in an asymmnetric fashion to target tissue surrounding a surgical extraction site. The apparatus includes an expandable outer surface element defining an apparatus spatial volume, a radiation source disposed within the apparatus volume, and a means for providing predetermined asymmnetric isodose profile within the target tissue.

In one configuration, asymmetric isodose curves are created in the target tissue by shaping or locating the radiation source so as to be asymmetrically placed with respect to a

longitudinal axis of the apparatus. In one example of an apparatus having this configuration, an inner volume containing a liquid radioisotope is asymmetrically placed within the apparatus volume so as to result in an isodose profile in the target tissue that is asymmetric about the longitudinal axis of the apparatus.

In another example, the radiation source comprises a plurality of spaced apart solid radioactive particles disposed within the apparatus volume and arranged to provide a predetermined asymmetric isodose curve within the target tissue. In one particular example, the plurality of spaced apart radioactive particles are provided on a single elongate member that is shaped so that some of the radioactive particles are farther from the longitudinal axis of the apparatus than others. In other particular examples, a plurality of members carrying radioactive particles are provided with at least one of the members being shaped so as to place at least one radioactive particle asymmetrically with respect to the longitudinal axis of the apparatus.

An interstitial brachytherapy apparatus of the invention may also be implemented in a device having an expandable outer surface defining an apparatus volume, a radiation source disposed within and spaced apart from the expandable outer surface, and at least one asymmnetric radiation shield spaced apart from the radiation source, the asymmetric radiation shielding resulting in predetermined asymmetric isodose curves with in the target tissue. In one embodiment, radiopaque shielding is provided on a portion of the expandable outer surface. In another embodiment, the radiation source is encompassed within a second, inner surface within the apparatus volume, with radiopaque shielding provided on at least a portion of the inner surface. In still further embodiments, one or more radiation shields are spaced apart from the radiation source and within the apparatus volume to achieve the desired asymmetric isodose distribution within the target tissue.

The invention also provides a method for treating a proliferating tissue disease using interstitial brachytherapy at an internal body location. The method includes surgically creating access to the proliferating tissue within a patient and surgically resecting at least a portion of the proliferating tissue to create a resection cavity within body tissue. An interstitial brachytherapy apparatus for delivering radioactive emissions as described above is then provided and intra-operatively placed into the resection cavity. After a prescribed absorbed dose has been delivered to tissue surrounding the apparatus, the apparatus is removed. The radioactive source material may be placed into the interstitial brachytherapy apparatus after the apparatus is placed in the resection cavity, and may be removed before the apparatus is removed. The method has particular applications to brain and breast cancers.

DESCRIPTION OF THE DRAWINGS

The foregoing features, objects and advantages of the invention will become apparent to those skilled in the art from the following detailed description of a preferred embodiment, especially when considered in conjunction with the accompanying drawings in which:

FIG. **1** is a side view of an interstitial brachytherapy apparatus of the invention for delivering asymmetric radioactive doses to body tissue;

FIG. **2** is a cross-sectional view taken along the line 2—2 in FIG. 1;

FIG. **3** is a side view of an additional embodiment of an interstitial brachytherapy apparatus of the invention;

FIG. **3A** is an end view of the interstitial brachytherapy apparatus of FIG. **3**;

FIG. **4** is a side view of an additional embodiment of an interstitial brachytherapy apparatus of the invention;

FIG. **5** is a side view of an interstitial brachytherapy apparatus of the invention configured for use with a liquid radiation source.

FIG. **6** is a side view of an interstitial brachytherapy device of the invention employing radiopaque coatings;

FIG. **7** is a side view of an interstitial brachytherapy device of the invention employing radiopaque coating and a liquid radiation source; and

FIGS. **8** and **9** are end views of interstitial brachytherapy devices of the invention employing radiopaque shields.

DESCRIPTION OF THE PREFERRED EMBODIMENT

A surgical instrument **10** for providing radiation treatment to proliferative tissue in a living patient is illustrated in FIG. **1**. Surgical instrument **10** includes a tubular body member **12** having first and second lumens **14** and **16** (FIG. **2**) extending from proximal ports **18** and **20** in a molded hub **22**. The first lumen **14** carries a radioactive source **24** and second lumen **16** communicates with inflation port **26** formed through the side wall of the tube **12**.

Affixed to the tubular body **12** proximate the distal end **28** thereof is an outer spatial volume **30** defined by an outer polymeric film barrier **32** that is appropriately spaced from the radioactive source **24**. Outer volume **30** encompasses inflation port **26**. With no limitation intended, the distensible polymeric film walls may comprise a biocompatible, radiation resistant polymer, such as silastic rubbers, polyurethanes, polyethylene, polypropylene, polyester, or PVC. The outer spatial volume **30** may be filled with air, saline or, alternatively, a radiation absorbing fluid, such as a contrast media used in angiography. Alternatively, the surface of outer volume **30** need not be a solid material. For example the surface of the outer volume **30** could be an expandable cage formed from a shape memory metal, such as nitinol, or a suitable plastic, such as an expandable polyethylene cage. Such a cage can be formed in the desired shape to conform to a particular isodose profile, contracted for delivery to the target site in vivo, then expanded to cause the tissue surrounding the surgically resected region to take the appropriate shape. The size of the outer spatial volume **30** generally will correspond approximately to the amount of tissue resected. For some applications, the size of the outer spatial volume **30** may be slightly smaller than the resected volume while for other applications, the outer spatial volume will be slightly larger than the resected volume, allowing the expandable surface of the outer spatial volume to urge tissue on the surface of the resected region into the appropriate shape to promote an even dose distribution around the outer spatial volume in the target tissue. In typical applications, the outer spatial volume has a diameter of approximately 2 to 6 centimeters.

Radiation source **24** comprises a wire **34** having one or more solid radioactive particles **36** located on the wire **34**. For example, radioactive micro spheres of the type available from the 3M Company of St. Paul, Minn., may be used as the solid radioactive particles. Such a solid radioactive particle configuration offers an advantage in that it allows a wider range of radionuclides than if one is limited to liquids. Solid radionuclides that could be used with the delivery device of the present invention are currently generally available as brachytherapy radiation sources. Examples of

radioactive materials which can be selected by a person of ordinary skills in the art for use with the present invention may be found in Tables 1 to 4 of PCT Publication WO 97/19723, which is hereby incorporated by reference.

The, radioactive source **24** can either be preloaded into the catheter at the time of manufacture, or loaded into the device after it has been implanted into the space formerly occupied by the excised tumor. If loaded after implantation, the solid radiation emitting material **36** can be inserted through lumen **14** on a wire **34**, for example using an afterloader (not shown).

Radiation source **24** has an asymmetric configuration with respect to a longitudinal axis **38** of the instrument **10**. That is, radiation source **24** is shaped so as to result in an isodose profile **40** that varies radially about the longitudinal axis **38**. More simply, the isodose profile **40** of FIG. **1** has a shorter radius from the longitudinal axis **38** on the top side of the instrument **10** as shown in FIG. **1** than on the bottom side. The asymmetrically shaped isodose curve **40** may be created by providing a plurality of solid radioactive particles **36** on a curved wire **34** in a spaced apart relationship. This configuration will result in certain of the solid radioactive particles **36** being farther from the longitudinal axis **38** of the instrument **10** than others, and will result in the illustrated asymmetric isodose profile **40**. One way to provide the illustrated radioactive source **24** configuration is to form wire **34** from a solid or tubular shape memory alloy such as nickel-titanium alloys known in the art to have such properties. Wire **34** can then be preformed to the desired shape, can be compressed into a substantially straight configuration to pass through lumen **14**, and will resume its desired shape once inside volume **30** where wire **34** will be free from steric constraints imposed inside the lumen **14**. The resulting asymmetric isodose curve **40** can be further tailored by using solid radioactive particles **36** having differing specific activities to achieve the desired dosing.

In,one embodiment, volume **30** and barrier **32** act to separate target tissue from the radiation source **24**. Ideally, radiation therapy should make use the inherent difference in radiosensitivity between the tumor and the adjacent normal tissues to destroy cancerous tissue while causing minimal disruption to surrounding normal tissues. At high doses of radiation, however, the percentage of exposed cells that survive treatment decreases with first-order kinetics in proportion to increasing radiation dose. With increasing cell death comes increasing risk of necrosis or tissue death in healthy tissue that is treated with a high dose of radiation. Accordingly, it is desirable to keep the maximum radiation dose delivered by the brachytherapy apparatus as low as possible while still delivering the desired therapeutic dose to the desired range of tissue. One method for achieving this result is to provide a "hotter" radiation source in a spaced apart relationship to the target tissue. In this way, because the intensity of the radiation emitted by a source drops with the square of the distance from the source, the effective dosage may be maintained below necrosis levels in target tissue closest to the interstitial brachytherapy apparatus while providing the required dosage to a greater depth into the target tissue. (See, e.g., U.S. Pat. No. 5,913,813 which is hereby incorporated by reference in its entirety.) The capability of the apparatus of the invention to deliver absorbed doses deeper into the target tissue than prior interstitial brachytherapy devices while controlling the dose in proximity to the apparatus to reduce or eliminate the risk of healthy tissue necrosis allows for the use of brachytherapy in a greater number of cases.

For example, it is desirable to provide an interstitial brachytherapy device configured to provide a dose in a therapeutic range, say between 40 to 60 Gray, at a distance between 0.5 and 1.0 cm from the outer spatial volume for an outer spatial volume having a diameter of 4.0 cm and being in contact with the resection cavity wall. In a typical embodiment, the radioactive source material ranges from approximately 150 to 450 mCi in activity and encompasses most of the target treatment area with a 0.4 to 0.6 Gray/hour isodose contour. At this treatment rate, treatment may be completed in approximately 3 to 7 days, or more commonly, in approximately 3 to 5 days.

In some applications, the desired dosing profile is consistent with the shape of the outer volume **30**. That is, the absorbed dose within the target tissue at points equidistant from the surface **32** of the outer spatial volume **30** should be substantially uniform in substantially every direction. Put another way, the three dimensional isodose profiles generated by the radiation source should be substantially similar in shape to the outer spatial volume **30**. Where the apparatus of the invention is deployed in soft tissue, it may also be important for the surface **32** of the outer spatial volume **30** to be sufficiently firm so as to force the target tissue to take on the shape of the surface **30** so that the desired relationship between the isodose profiles and the target tissue is achieved

While the interstitial brachytherapy device **10** of FIG. **1** may employ these techniques to positive effect, this device specifically alters the isodose profile for applications where particularly sensitive tissue or other concerns result in a desire to limit the dosage on one or more sides of the device as illustrated by isodose curve **40**.

In a further embodiment of the brachytherapy device **50** of the invention, illustrated in FIG. **3**, three solid radiation particles **52** are provided in a linear portion **54** of radiation source **56**, while two additional radiation particles **52** are provided on co-planar extending portions **58**, **60** of radiation source **56**. An end view of the device **50** of FIG. **3** is shown in FIG. 3A with extending portions **58**, **60** provided in a single plane **62**, and resulting in isodose profile **64**. A second inner, expandable surface **66** can also be provided within outer surface **68**; the inner surface **66** enclosing the entirety of radiation source **56**.

By providing extending portions **58**, **60** having radioactive particles in the indicated co-planar relationship, areas of reduced dosage can be created on opposed sides of the device while maintaining symmetric dosing in all other directions. Of course, the number of sources and their configuration can be changed to create a desired asymmetric dosage. For example, an additional source could be added, for example above plane **62**, to result in a symmetric isodose profile in all directions except the direction below the plane **62** which would have a lower dosage.

An additional device **80** of the invention, shown in FIG. **4**, includes a radiation source **82** that is made up of three wires **84**, **86**, **88**, each having a plurality of solid radiation particles. Wire **86** is a straight wire extending along the longitudinal axis **90** of the device, while wires **84**, **88** each curve as wire **34** described above with respect to FIG. **1**. Wires **84**, **88** are coplanar, resulting in an isodose profile **92** that is similar to isodose profile **64** of FIG. 3A. That is, the isodose profile will be symmetric in the plane in which the wires **84**, **88** are disposed, but will have areas of reduced dosage in directions transverse to that plane (i.e., in FIG. **4**, in the directions into and out of the page). As with the device **50** of FIGS. **3** and 3A, device **80** can be configured with more or fewer wires **84**, **86**, **88**, and can be provided in configurations other than the depicted co-planar configuration in order to achieve desired asymmetric isodose profiles.

The asymmetric dosing effect achieved by the devices described above can also be achieved using a liquid radiation source. For example, device **100**, illustrated in FIG. **5**, has an outer surface **102** defining an outer volume **104** and an inner surface **106** defining an inner volume **108**. The inner surface **106** is asymmetrically shaped or located with respect to the longitudinal axis **110** of the device **100** so as to result in the desired asymmetric dosing when the inner volume **108** is filled with a radioactive fluid. The inner volume **108** is spaced apart from the outer surface **102** and can be filled with a material containing a predetermined radionuclide, for example, I-125, I-131, Yb-169 or other source of radiation, such as radionuclides that emit photons, beta particles, gamma radiation, or other therapeutic rays. The radioactive material contained within the inner volume **108** can be a fluid made from any solution of radionuclide(s), e.g., a solution of Ir-192, I-125 or I-131. A radioactive fluid can also be produced using a slurry of a suitable fluid containing small particles of solid radionuclides, such as Au-198, Y-90. Moreover, the radionuclide(s) can be embodied in a gel. One radioactive material useful in the invention is Iotrex™, a sterile single use, non-pyrogenic solution containing sodium 3-(^{125}I)iodo-4-hydroxybenzenesulfonate (^{125}I-HIBS), available from Proxima Therapeutics, Inc. of Alpharetta, Ga. The inner volume **108** may be filled with radioactive fluid through port **112**. Similarly, outer volume **104** can be filled on inflated using port **114**.

A desired asymmetric dosing profile having the dosing characteristics described above may also be created by using asymmetric shielding between the radiation source and the target tissue as illustrated in FIGS. **6** through **9**. In the device **120** of FIG. **6**, a balloon **122** is located on the distal end of catheter **124**. Radioactive particles **126** are disposed along the longitudinal axis **128** of the device. A portion of the surface, either inner or outer, of balloon **122** is coated with a radiopaque material **130** to result in asymmetric isodose curve **132**. Radiopaque materials suitable for coating onto a polymeric surface of balloon **122** include, for example, barium, tungsten, bismuth, tantalum and tin.

A further device **140** having radiopaque shielding **142** is illustrated in FIG. **7**. Device **140** includes an outer volume surface **144** and an inner volume surface **146**. Inner surface **146** may contain a liquid radiation source, or may enclose one or more solid particles as used in device **120** (FIG. **6**). In device **140**, the radiopaque material **142** is coated onto a portion of either the inner or outer side of the inner volume surface **146**, resulting in a desired asymmetric isodose profile **148**.

Additional devices **160**, **180** of the invention having radiation shielding **162** are illustrated in FIGS. **8** and **9**, respectively. In these devices **160**, **180**, one or more radiation shields **162** are provided between and spaced apart from a radiation source (not shown) located along a longitudinal axis **164** of the device and the target tissue, which will be located outside of expandable surface **166**. The radiation source can include a liquid or a solid radiation source as described above. Shields **162** can be formed from radiopaque materials including those described above with respect to the radiopaque coating and can extend longitudinally from a base on the device located within the expandable surface **166**.

As shown in FIG. **8**, device **160** has two radiation shields **162** on opposed sides of catheter **168**. This configuration results in lower radiation dosing on the two sides of the device **160** on which the shields **162** are located as shown by isodose curve **170**. Device **180** (FIG. **9**) has a single radiation shield **162** resulting in an asymmetric isodose curve **182** as shown. A person or ordinary skill in the art will recognize that other configurations may be employed to achieve desired isodose curves.

The interstitial brachytherapy apparatus of the invention can be used in the treatment of a variety of malignant tumors, and is especially useful for in the treatment of brain and breast tumors.

Many breast cancer patients are candidates for breast conservation surgery, also known as lumpectomy, a procedure that is generally performed on early stage, smaller tumors. Breast conservation surgery is typically followed by postoperative radiation therapy Studies report that 80% of breast cancer recurrences after conservation surgery occur near the original tumor site, strongly suggesting that a tumor bed "boost" of local radiation to administer a strong direct dose may be effective in killing any remaining cancer and preventing recurrence at the original site. The apparatus described herein can be used for either the primary or boost therapy. Numerous studies and clinical trials have established equivalence of survival for appropriate patients treated with conservation surgery plus radiation therapy compared to mastectomy.

Surgery and radiation therapy are also the standard treatments for malignant solid brain tumors. The goal of surgery is to remove as much of the tumor as possible without damaging vital brain tissue. The ability to remove the entire malignant tumor is limited by its tendency to infiltrate adjacent normal tissue. Partial removal reduces the amount of tumor to be treated by radiation therapy and, under some circumstances, helps to relieve symptoms by reducing pressure on the brain.

A method according to the invention for treating these and other malignancies begins by surgical resection of a tumor site to remove at least a portion of the cancerous tumor and create a resection cavity. Following tumor resection, but prior to closing the surgical site, the surgeon intraoperatively places an interstitial brachytherapy catheter apparatus, having an inner spatial volume and an outer spatial volume as described above but without having the radioactive source material loaded, into the tumor resection cavity. Once the patient has sufficiently recovered from the surgery, the interstitial brachytherapy catheter is loaded with a radiation source. The radioactive source dwells in the catheter until the prescribed dose of radiotherapy is delivered, typically for approximately a week or less. The radiation source is then retrieved and the catheter is removed. The radiation treatment may end upon removal of the brachytherapy apparatus, or the brachytherapy may be supplemented by further doses of radiation supplied externally.

It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention, including, but not limited to, combinations of elements from different embodiments found herein. All references cited herein are expressly incorporated by reference in their entirety.

What is claimed is:

1. An interstitial brachytherapy apparatus for treating target tissue surrounding a surgical extraction comprising:

an expandable outer surface defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated;

a radiation source disposed completely within the expandable outer surface and located so as to be spaced apart from the apparatus volume, the radiation source further being asymmetrically located and arranged within the expandable surface to provide predetermined asymmetric isodose curves with respect to the apparatus volume.

2. A surgical apparatus for providing radiation treatment to target tissue comprising:

an expandable outer surface defining an apparatus volume;

a radiation source replaceably disposable within the expandable outer surface, the radiation source comprising a plurality of solid radiation sources arranged to provide predetermined asymmetric isodose curves within the target tissue, the plurality of solid radiation sources being provided in a spaced apart relationship on a single elongate member, the single elongate member being shaped to provide asymmetric placement of the spaced apart solid radiation sources with respect to a longitudinal axis through the apparatus volume.

3. The apparatus of claim **2**, further comprising a catheter in communication with the apparatus volume, the elongate member extending through the catheter into the apparatus volume.

4. The apparatus of claim **3**, wherein the elongate member is formed of a shape memory alloy, the elongate member being shaped to provide asymmetric placement of the spaced apart solid radiation sources, taking on a substantially straight shape while being inserted through the catheter to the apparatus volume, and resuming an asymmetric shape when extended into the apparatus volume.

5. A surgical apparatus for providing radiation treatment to target tissue comprising:

an expandable outer surface defining an apparatus volume;

a radiation source replaceably disposable within the expandable outer surface, the radiation source comprising a plurality of solid radiation sources arranged to provide predetermined asymmetric isodose curves within the target tissue, wherein at least one of the plurality of solid radiation sources has a different specific activity from at least one other solid radiation source.

6. A surgical apparatus for providing radiation treatment to target tissue comprising:

an expandable outer surface defining an apparatus volume;

a radiation source replaceably disposable within the expandable outer surface, the radiation source comprising a plurality of solid radiation sources arranged to provide predetermined asymmetric isodose curves within the target tissue, the plurality of radiation sources being provided on at least two elongate members extending into the apparatus volume, at least one of the elongate members being shaped to provide asymmetric placement of a radiation source with respect to a longitudinal axis through the apparatus volume.

7. The apparatus of claim **6**, wherein each of the at least two elongate members includes a plurality of solid radiation sources provided in a spaced apart relationship.

8. The apparatus of claim **1**, wherein the expandable outer surface is sufficiently rigid to deform the target tissue into the shape of the expandable outer surface, causing the predetermined asymmetric isodose curves to penetrate into the target tissue to a prescribed depth.

9. An interstitial brachytherapy apparatus for treating target tissue surrounding a surgical extraction comprising:

an expandable outer surface having a base and defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated;

a radiation source disposed completely within and spaced apart from the expandable outer surface; and

an asymmetric radiation shield spaced apart from the radiation source, the asymmetric radiation shield providing predetermined asymmetric isodose curves with respect to the apparatus volume.

10. The apparatus of claim **9**, wherein the asymmetric radiation shield comprises a radio-opaque material disposed on only a portion of the expandable outer surface.

11. The apparatus of claim **10**, wherein the expandable outer surface comprises an inflatable balloon.

12. The apparatus of claim **11**, wherein the radiation shield comprises a barium material disposed a portion of the inflatable balloon.

13. The apparatus of claim **9**, further comprising at least one radiation shield extending from the base of the expandable outer surface toward an opposite end of the expandable surface, the shield being in between and spaced apart from the radiation source and the expandable outer surface, the shield forming a radio-opaque barrier between a portion of the radiation source and the target tissue.

14. The apparatus of claim **13**, wherein the radiation shield comprises two shields provided on opposite sides of the radiation source.

* * * * *

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Kirsten Blue, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On May 21, 2008, I served a copy(ies) of the following document(s):

DECLARATION OF ADAM D. HARBER IN SUPPORT OF DEFENDANT SENORX, INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY ('142 PATENT, CLAIMS 1 AND 8)

on the parties to this action by the following means:

Henry C. Su (suh@howrey.com) Katharine L. Altemus (altemusk@howrey.com) HOWREY LLP 1950 University Avenue, 4th Floor East Palo Alto, CA 94303 Telephone: (650) 798-3500 Facsimile: (650) 798-3600	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP
Matthew Wolf (wolfm@howrey.com) Marc Cohn (cohnm@howrey.com) HOWREY LLP 1229 Pennsylvania Avenue, NW Washington, DC 20004 Telephone: (202) 783-0800 Facsimile: (202) 383-6610	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP

☒ (BY MAIL) I placed the sealed envelope(s) for collection and mailing by following the ordinary business practices of Wilson Sonsini Goodrich & Rosati, 12235 El Camino Real, Ste. 200, San Diego, CA. I am readily familiar with WSGR's practice for collecting and processing of correspondence for mailing with the United States Postal Service, said practice being that, in the ordinary course of business, correspondence with postage fully prepaid is deposited with the United States Postal Service the same day as it is placed for collection.

☒ (BY ELECTRONIC MAIL) I caused such document(s) to be sent via electronic mail (email) to the above listed names and email addresses.

☒ (BY CM/ECF) I caused such document(s) to be sent via electronic mail through the Case Management/Electronic Case File system with the U.S. District Court for the Northern District of California.

I declare under penalty of perjury under the laws of the United States that the above is true and correct, and that this declaration was executed on May 21, 2008.

Kirsten Blue

F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399
Email: amahaney@wsgr.com

Bruce R. Genderson (*admitted pro hac vice*)
Aaron P. Maurer (*admitted pro hac vice*)
Rachel Shanahan Rodman (*admitted pro hac vice*)
Adam D. Harber (*admitted pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant and Counterclaimant
SENORX, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORP., and HOLOGIC L.P., Plaintiffs, v. SENORX, INC., Defendant.	CASE NO.: 08-CV-0133 RMW **[PROPOSED] ORDER GRANTING DEFENDANT SENORX, INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY ('142 PATENT, CLAIMS 1 AND 8)**
SENORX, INC., Counterclaimant, v. HOLOGIC, INC., CYTYC CORP., and HOLOGIC L.P., Counterdefendants.	

The Court having considered Defendant SenoRx, Inc.'s Motion for Partial Summary Judgment of Invalidity, the Memorandum in Support thereof, and the attached exhibits, and any Opposition thereto, any reply, and for good cause shown;

IT IS HEREBY ORDERED that SenoRx's Motion for Partial Summary Judgment of Invalidity is GRANTED; and

FURTHER ORDERED that Claims 1 and 8 of U.S. Patent No. 6,482,142 are invalid.

SO ORDERED.

Dated: _____, 2008

By: _____
Hon. Ronald M. Whyte
United States District Judge

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Kirsten Blue, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On May 21, 2008, I served a copy(ies) of the following document(s):

[PROPOSED] ORDER GRANTING DEFENDANT SENORX, INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY ('142 PATENT, CLAIMS 1 AND 8)

on the parties to this action by the following means:

Henry C. Su (suh@howrey.com) Katharine L. Altemus (altemusk@howrey.com) HOWREY LLP 1950 University Avenue, 4th Floor East Palo Alto, CA 94303 Telephone: (650) 798-3500 Facsimile: (650) 798-3600	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP
Matthew Wolf (wolfm@howrey.com) Marc Cohn (cohnm@howrey.com) HOWREY LLP 1229 Pennsylvania Avenue, NW Washington, DC 20004 Telephone: (202) 783-0800 Facsimile: (202) 383-6610	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP

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Kirsten Blue